

Electronic Patient Information Leaflets

Enhancing patient safety and building supply resilience

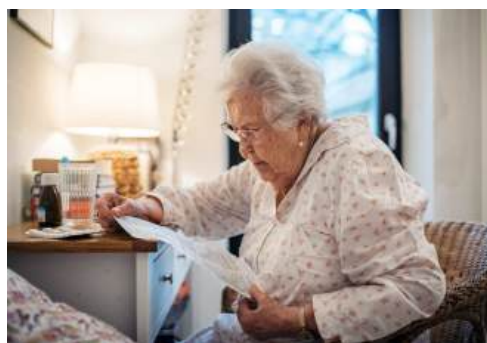
Patient Information Leaflets (PILs) provide patients with key information about their medicines. They are intended to ensure safe, effective use by providing essential, regulated details about dosage, side effects, and ingredients. They empower patients to make informed decisions, ensure correct usage, and are a legal requirement for licensed medicines to improve health outcomes. However the current UK wide legislation from over 25 years ago requires a paper leaflet to be included in every box of medicines.

Technology and public expectations have now moved on. In the digital age, moving to electronic PILs (ePILs) offers considerable potential benefits including:

- improving patient safety;
- improving accessibility;
- reducing the environmental footprint; and
- helping to improve the resilience of the supply chain, addressing medicines shortages.

The use of ePILs aligns with a strategic shift envisioned for the NHS – moving from 'analogue to digital'. Any change must also meet the needs of those who may find it more difficult to access digital services.

Introducing ePILs requires updated regulation and work with the industry to roll out ePILs, harness the benefits, and to ensure patient awareness.



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PATIENT INFORMATION LEAFLETS

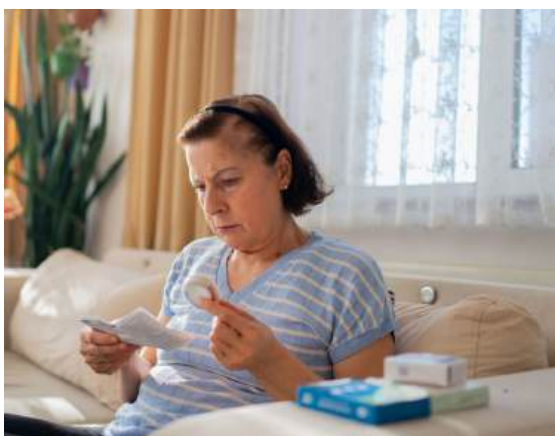
Providing patients with the information they need about the medicines they are prescribed or buy is essential. Accurate information is empowering. It can support patients to take medicines safely and understand when to raise any concerns they may have.

PAPER PILs – AN ANALOGUE SOLUTION IN A DIGITAL AGE?

Providing Patient Information leaflets (PILs) with every packet, box or bottle of medicine has been a legal requirement in the UK since 1999. [1] The requirement is part of the Human Medicines Regulations 2012. [2] PILs contain a considerable amount of information including:

- Information on the medicine itself (the active substance(s), and strength of the product);
- The conditions for which the medicine is authorised;
- Dosage and how the medicine should be taken;
- Information on how the medicine should not be used, precautions, warnings; interactions with other medicines;
- Description of possible side effects; and
- Additional information (including storage conditions, and details of the manufacturer).

Research indicates that patients are not necessarily accessing information from the paper PIL as intended:

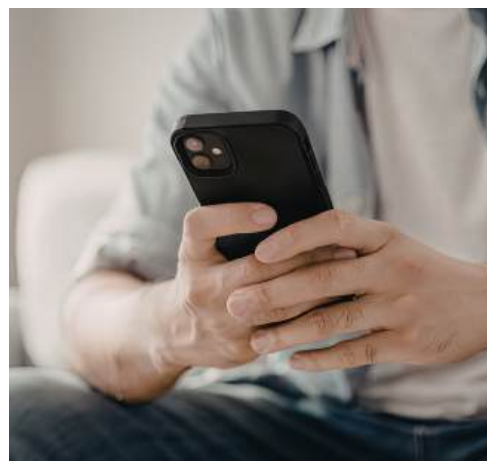


- Only **13%** of patients report paper-based information as a trusted source of medicines information. [3]
- A survey of nearly 3,000 patients indicated that less than 50% of them always or often read the patient information leaflet. [3]
- **Six in ten** patients reported a need for further information 10 days after starting a new long-term medicine. [4]
- Patients taking long-term medicines make less use of PILs, with only **10%** of patients reading the information when they receive repeat medicines. [3]

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In a digital age, patients are increasingly turning to online sources to better understand their health conditions and medicines, alongside a trusted healthcare professional's advice. [3] This may include NHS websites, search engines, social media, or AI. In so doing, patients are bypassing the highly regulated information contained in PILs.

It is important that patients have access to the information they need about their medicines. This has historically been done through paper PILs. Advances in technology, and insights on how paper leaflets are used, means there is real opportunity for change. This can improve the ease of access to information for patients offering potential improvements in the use of medicines.



ELECTRONIC PILs – BRINGING PATIENT INFORMATION INTO THE 21ST CENTURY

Moving from 'analogue to digital' is one of the governments three strategic shifts for the NHS. The government's 10-Year plan for the NHS outlines a desire to harness the digital revolution and "create the most digitally accessible health system in the world". [5] This plan includes allowing patients to manage their medicines through the NHS App by 2028.

Changing to a digital-first approach for electronic Patient Information Leaflets (ePILs), will transform the way patients interact with information about their medicines. A survey found that 71% of people would be happy to access and read a patient information leaflet online. [6] The ability to use ePILs instead of paper based PILs would offer considerable benefits – to patients, the supply chain, the health system and the environment.

This change would bring the UK into line with other countries including Australia, New Zealand, Japan, Singapore and Canada, who are already taking a digital-first approach or moving faster towards it.

THE BENEFITS OF ePILs

1. PATIENT SAFETY

Electronic PILs can offer routes to improving patient understanding and support adherence of their medicines. Better informed patients have the potential to reduce self-administered medication errors (e.g., misunderstanding the medicine dosage), maximise the intended benefits of the medicine, and ultimately improve health outcomes.



Through ePILs, patients would be able to access the very latest safety information. Patients would have immediate access to updates made to PILs through ongoing safety reviews or following any medicines safety notifications from the Medicines and Healthcare products Regulatory Agency (MHRA). The current lag time between identifying changes and the updated paper leaflet being available in a pack of medicine can be months. Interim measures are currently put in place to support patients. The most efficient solution to ensure patient access to the current information would be easy digital access.

With ePILs, when urgent safety variations are needed, patient information content could be updated, as soon as it is approved. This would ensure patients are accessing the most up to date information available at all times.

2. ACCESSIBILITY

Introducing ePILs would allow new approaches to support health literacy. ePILs can be accessed easily from a computer, tablet, or smartphone. People with accessibility needs, e.g., sight or hearing loss, may be able to use assistive technology to access information. ePILs could include adaptable font sizes or searchable content, supporting patients trying to access crucial information. There is also potential for digital information to be accessed in different languages.

By providing easy-to-access and easy-to-understand information, ePILs can increase patient engagement and help to ensure medicines are taken as advised. ePILs offer new routes to access key information, that can continue to develop with new technologies. Of course, any solution must also meet the needs of those who cannot access digital tools.

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3. ENVIRONMENTAL

Globally, **over 100 billion paper leaflets** are produced every year. This requires paper produced from **9 million trees**. Producing this many paper leaflets uses the same amount of energy required to fuel 50,000 homes for a year. [7]

In 2024/25, community pharmacies across GB dispensed nearly 1.4 billion prescription items, and almost 1 billion packs of over-the-counter products are sold each year. [8] It is estimated this equates to nearly 3.5 billion paper PILs.



Allowing ePILs instead of paper leaflets would drastically reduce paper usage and subsequent waste.

In some cases, changes to patient information means that medicines must be recalled (or even destroyed) to update the paper leaflet in the box. With ePILs there would be less medicines waste, as these boxes would not be recalled – the information would be updated electronically. Using ePILs may also reduce the size and weight of medicine packs, in turn lowering the environmental footprint and cost associated with transport.

Empowering patients to improve medicines adherence through better information could also lead other environmental benefits. For example, hospital admissions and outpatient appointments for acute care have significant environmental impact (125kg CO₂e per bed day and 76 kg CO₂e per outpatient appointment for acute care). [9] Supporting patients to take their medicines as intended, through improved access to patient information this could mean fewer hospital admissions, less medicines waste (medicines that are not taken as intended) and potentially reduced demand on stretched healthcare systems by avoiding a deterioration in health. This would also provide economic benefits. [10]

4. MEDICINES RESILIENCE

Recent examples of medicines shortages have highlighted challenges with resilience across the supply chain. **A transition to ePILs would help manufacturers streamline production, supporting with resilience and preventing some avoidable medicine shortages.** The transition to ePILs would reduce the time needed to develop, review and update printed leaflets within each medicine pack. Current regulation means that when patient information requires updating some medicine packs may be ‘written off’ or otherwise not be available for the UK market. This could lead to creating a shortage where medicines are unavailable because information leaflets need reprinting.

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ePILs may allow patient information to be accessed in different languages. This would mean medicines could be supplied to different countries more easily (e.g. parallel import of medicines between countries). This improves efficiencies and resilience.

A transition to ePILs could also help increase the UK's attractiveness to global medicines manufacturers, ensuring the UK remains a hub for life sciences.

NEXT STEPS

The UK is in a strong place to accelerate the transition to ePILs, given recent success with the implementation of the NHS App for England and the desire as part of the 10 Year Health Plan for England [5] to move from "analogue to digital".

We urge policymakers to:

- 1 Update regulation to permit the use of ePILs in place of paper leaflets.
- 2 Work with industry to outline an ambitious roadmap for the rollout and use of ePILs.
- 3 Work with industry to harness the accessibility benefits that ePILs bring and aligning with changes to the NHS app in England and planned digital platforms and developments in Scotland and Wales. Any changes should ensure that patients who wish to access paper-based information can continue to do so.
- 4 Ensure there is a widespread patient awareness programme to harness public support for digital access to patient information leaflets as a trusted source of information.

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MEDICINES SUPPLY RESILIENCE GROUP



MEDICINES SUPPLY
RESILIENCE GROUP

The MSRSG brings together representatives from all parts of the supply chain, covering manufacturing, wholesaling and community pharmacy.

Members include AAH Pharmaceuticals, Community Pharmacy (CPE), Healthcare Distribution Association (HDA), Medicines UK, National Pharmacy Association (NPA) and Proprietary Association of Great Britain (PAGB).

The Group has also been attended by representatives from the following organisations, who have participated in discussions but do not act as decision-makers on MSRSG policy positions or endorse the MSRSG's external publications or its recommendations:

- Department of Health and Social Care
- Medicines and Healthcare Regulatory Agency (MHRA)
- NHS England
- NHS Nottingham and Nottinghamshire

The MSRSG is currently sponsored by AbbVie, Accord and Viatrix.



The MSRSG is hosted by the Company Chemists' Association (CCA), the trade association for multiple pharmacies across Great Britain.



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